## REMARKS

Claims 1-18 are pending in the application. Claims 1-18 stand rejected.

In accordance with 37 C.F.R. 1.136(a), a two month extension of time is submitted herewith to extend the due date of the response to the Office Action dated October 21, 2003, for the above-identified patent application from January 21, 2003, through and including March 22, 2003. In accordance with 37 C.F.R. 1.17(a)(2), authorization to charge a deposit account in the amount of $210.00 to cover this extension of time request also is submitted herewith.

The rejection of Claims 1-18 under 35 U.S.C. § 112, first paragraph, is respectfully traversed. Claims 1, 12, and 14 have been amended to address the issues noted in the Office Action. Specifically, the Claims have been amended to recite that a fiber of an interferometric system is coupled to the distal end of the guide wire. Claims 2-11 depend from Claim 1, Claim 13 depend from Claim 12, and Claims 15-18 depend from Claim 14. For the reasons set forth above, Applicants respectfully request that the Section 112 first paragraph rejections of Claims 1-18 be withdrawn.

The rejection of Claims 1-4 and 7-11 under 35 U.S.C. § 102(e) as being anticipated by Tearney et al. is respectfully traversed.

Tearney et al. describes an imaging system where a stationary fiber within the device transmits light to an optical system where the light is transmitted through a lens and reflected using a beam director through a window. More specifically, a guidewire 334 is used to direct a catheter or endoscope through an artery or vein. The guidewire 334 includes a housing 342, forming a hollow elongated bore 343 within which a rotating optical fiber 344 extends. Formed at the distal end of the guidewire 334 is a flexible tip 363 preferably fabricated from a coiled biocompatible radiopaque material with a radiopaque tip 350. The flexible tip 363 typically extends approximately 4 cm beyond window 360 and may be covered with a smooth jacket 362. An optical system 354 is preferably positioned at a stationary area 340 in the guidewire, as the

moving tip 350 may make it difficult to obtain images or the presence of optics will reduce the flexibility of the tip. In another embodiment, the optical system includes one stationary fiber within the radiopaque tip of the guide wire. The optical radiation from the optical fiber 344 is transmitted to the optical system 354 where it is transmitted through a lens 356 and a beam director 358 and through the window 360. (See Tearney et al. at column 12, lines 10-40 and Figure 12.)

In addition, Tearney et al. describe a signal processing and control electronics and display unit 18 where an image of the structure is obtained and analyzed. (Column 4, lines 50-52). A movement detector can further be coupled to the longitudinal scanning mechanism 128 to detect the position of the reference reflector 12 in order to achieve uniform motion of the reference reflector 12 or to sense the actual velocity profile and correct for the non-uniform velocity in electronic processing unit 18. (Column 6, lines 49-55). However, a circuit for generating Doppler shift information configured to detect neovascular flow through the tissue by revealing relative changes in blood flow velocity is neither described, nor suggested.

Claim 1 recites an apparatus configured to guide a guide wire through body tissue which comprises "a guide wire having a first proximal end and second distal end" and "at least one interferometric guidance system". The interferometric guidance system comprises "a fiber comprising an end coupled to said guide wire distal end" and "a circuit for generating Doppler shift information configured to detect neovascular flow through the tissue by revealing relative changes in blood flow velocity at the guide wire distal end, said interferometric guidance system configured for generating interference information from body tissue."

Tearney et al. do not describe nor suggest an apparatus where a fiber of an interferometric guidance system is coupled to said guide wire distal end. Rather, Tearney et al. suggest a guidance system having a stationary fiber within a radiopaque tip of a guide wire. In addition Tearney et al. Neither describe, nor suggest a circuit for generating Doppler shift information

which is utilized to detect neovascular flow through the tissue by revealing relative changes in blood flow velocity. For these reasons, Claim 1 is submitted to be patentable over Tearney et al.

Claims 2-4 and 7-11 depend, directly or indirectly, from independent Claim 1. When the recitations of Claims 2-4 and 7-11 are considered in combination with the recitations of Claim 1, Applicants submit that dependent Claims 2-4 and 7-11 likewise are patentable over Tearney et al.

For the reasons set forth above, Applicants respectfully request that the Section 102 rejection of Claims 1-4 and 7-11 be withdrawn.

The rejection of Claims 5, 6, 12, and 13 under 35 U.S.C. § 103 as being unpatentable over Tearney et al. in view of Peterson et al. is respectfully traversed.

Tearney et al. is described above. Peterson et al. (U.S. Patent No. 5,549,114) describe an apparatus for performing blood flow studies wherein the Doppler processing circuitry includes a frequency-to-voltage converter. More specifically, Peterson et al. describe an apparatus which measures the speed of blood traveling through blood vessels which includes a source 510 comprising a superluminescent light emitting diode which is focused through a pinhole aperture or into a single mode optical fiber to provide good spatial coherence. The apparatus further includes a detector 580 comprising a photodiode or similar device, a reference mirror 560 comprising a retroreflector, and an analyzer 590 comprising a gated timer and a frequency to voltage converter or a microprocessor controller or equivalent apparatus. See Peterson et al. Column 9, lines 10-20.

Claims 5 and 6 depend from Claim 1 which recites an apparatus configured to guide a guide wire through body tissue which comprises "a guide wire having a first proximal end and second distal end" and "at least one interferometric guidance system". The interferometric guidance system comprises "a fiber comprising an end coupled to said guide wire distal end" and "a circuit for generating Doppler shift information configured to detect neovascular flow through

the tissue by revealing relative changes in blood flow velocity at the guide wire distal end, said interferometric guidance system configured for generating interference information from body tissue."

Tearney et al. in view of Peterson et al. do not describe nor suggest an apparatus where a fiber of an interferometric guidance system is coupled to said guide wire distal end. Rather, Tearney et al. suggest a guidance system having a stationary fiber within a radiopaque tip of a guide wire and Peterson et al. describe an apparatus for performing Doppler blood flow studies wherein the processing circuitry includes a frequency-to-voltage converter. For these reasons, Claim 1 is submitted to be patentable over Tearney et al. in view of Peterson et al.

Claims 5 and 6 depend, directly or indirectly, from independent Claim 1. When the recitations of Claims 5 and 6 are considered in combination with the recitations of Claim 1, Applicants submit that dependent Claims 5 and 6 likewise are patentable over Tearney et al. in view of Peterson et al.

Claim 12 recites an apparatus for detecting neovascular flow through an obstruction in a blood vessel. The apparatus comprises "a guide wire having a first proximal end and second distal end," "at least one interferometric guidance system comprising a fiber coupled to said guide wire distal end," "an interferometric apparatus coupled to said guide wire proximal end," "a broad band filter coupled to an output of said interferometric apparatus, said interferometric apparatus generating interferometric peaks of varying frequencies" and "a frequency-to-voltage converter coupled in series to said broad band filter."

Tearney et al. in view of Peterson et al. do not describe nor suggest an apparatus where a fiber of an interferometric guidance system is coupled to said guide wire distal end. Rather, Tearney et al. suggest a guidance system having a stationary fiber within a radiopaque tip of a guide wire and Peterson et al. describe an apparatus for performing Doppler blood flow studies wherein the processing circuitry includes a frequency-to-voltage converter. For these reasons, Claim 12 is submitted to be patentable over Tearney et al. in view of Peterson et al.

Claim 13 depends from independent Claim 12. When the recitations of Claim 13 are considered in combination with the recitations of Claim 12, Applicants submit that dependent Claim 13 likewise is patentable over Tearney et al. in view of Peterson et al.

The rejection of Claims 14 and 18 under 35 U.S.C. § 103 as being unpatentable over Izatt et al. in view of Tearney et al. is respectfully traversed.

Tearney et al. is described above. Izatt et al. describe a method for generating a velocity-indicating, tomographic image of a sample in an optical coherence tomography system includes the steps of (a) acquiring cross-correlation data from the interferometer; (b) generating a grayscale image from the cross-correlation data indicative of a depth-dependent positions of scatterers in the sample; (c) processing the cross-correlation data to produce a velocity value and location of a moving scatterer in the sample; (d) assigning a color to the velocity value; and (f) merging the color into the grayscale image, at a point in the grayscale image indicative of the moving scatterer's location, to produce a velocity-indicating, tomographic image.

Independent Claim 14 recites a method to determine neovascular flow through tissue in a vessel. The method comprises "using an apparatus configured to guide a guide wire through body tissue" "examining the vessel with the interferometric system" and "performing a Doppler shift analysis on frequencies of interference peaks generated by the interferometric system examining the vessel to determine the velocity of blood". The apparatus comprises a guide wire having a first proximal end and second distal end, and at least one interferometric guidance system comprising at least one stationary optical fiber coupled to the guide wire distal end."

Izatt et al. in view of Tearney et al. do not describe nor suggest a method for using an apparatus where a fiber of an interferometric guidance system is coupled to said guide wire distal end. Nor do Izatt et al. in view of Tearney et al. describe or suggest examining the vessel with the interferometric system and performing a Doppler shift analysis on frequencies of interference peaks generated by the interferometric system examining the vessel to determine the velocity of blood. Rather, Izatt et al. describe a method for generating a velocity-indicating, tomographic

image of a sample in an optical coherence tomography system and Tearney et al. suggest a guidance system having a stationary fiber within a radiopaque tip of a guide wire. For these reasons, Claim 14 is submitted to be patentable over Izatt et al. in view of Tearney et al.

Claim 18 depends from independent Claim 14. When the recitations of Claim 18 are considered in combination with the recitations of Claim 14, Applicants submit that dependent Claim 18 likewise is patentable over Izatt et al. in view of Tearney et al.

The rejection of Claims 15-17 under 35 U.S.C. § 103 as being unpatentable over Izatt et al. in view of Tearney et al. and further in view of Swanson et al. is respectfully traversed.

Izatt et al. and Tearney et al. are described above. Swanson et al. describe a method and apparatus for performing various optical measurements utilizing an optical coherence domain refrectometer (OCDR). A short coherence optical radiation source applies optical radiation through like optical paths to a sample and an optical reflector. The optical reflector is movable in accordance with a predetermined velocity profile to permit interferometric scanning of the sample, the resulting output having a Doppler shift frequency modulation. See Abstract. Swanson et al. describe a sinusoidal motion of a mirror 32. The Doppler shift is directly proportional to a change in velocity (2V/lambda) and since the motion is sinusoidal, the velocity varies as a sine function. Column 8, line 65 to Column 9, line 3.

Claims 15-17 depend from independent Claim 14. The method comprises "using an apparatus configured to guide a guide wire through body tissue" "examining the vessel with the interferometric system" and "performing a Doppler shift analysis on frequencies of interference peaks generated by the interferometric system examining the vessel to determine the velocity of blood". The apparatus comprises a guide wire having a first proximal end and second distal end, and at least one interferometric guidance system comprising at least one stationary optical fiber coupled to the guide wire distal end.".

Izatt et al. in view of Tearney et al. and further in view of Swanson et al. do not describe nor suggest a method for using an apparatus where a fiber of an interferometric guidance system is coupled to said guide wire distal end. Rather, Izatt et al. describe a method for generating a velocity-indicating, tomographic image of a sample in an optical coherence tomography system, Tearney et al. suggest a guidance system having a stationary fiber within a radiopaque tip of a guide wire, and Swanson et al. describe an optical reflector that is movable in accordance with a predetermined velocity profile to permit interferometric scanning of the sample, the resulting output having a Doppler shift frequency modulation. . For these reasons, Claim 14 is submitted to be patentable over Izatt et al. in view of Tearney et al. and further in view of Swanson et al.

Claims 15-17 depend from independent Claim 14. When the recitations of Claims 15-17 are considered in combination with the recitations of Claim 14, Applicants submit that dependent Claims 15-17 likewise are patentable over Izatt et al. in view of Tearney et al. and further in view of Swanson et al.

In addition to the reasons given above, Applicants further traverse the rejections of Claims 5, 6, 12, and 13 under 35 U.S.C. § 103(a) as being unpatentable over Tearney et al. in view of Peterson et al., the rejection of Claims 14 and 18 under 35 U.S.C. § 103(a) as being unpatentable over Izatt et al. in view of Tearney et al., and the rejection of Claims 15-17 under 35 U.S.C. § 103(a) as being unpatentable over Izatt et al. in view of Tearney et al. and further in further view of Swanson et al.

The Section 103 rejection of the presently pending claims are not a proper rejections. As is well established, obviousness cannot be established by combining the teachings of the cited art to produce the claimed invention, absent some teaching, suggestion, or incentive supporting the combination. None of Tearney et al., Peterson et al., Izatt et al., or Swanson et al., considered alone or in combination, describe or suggest the claimed combination. Furthermore, in contrast to the assertion within the Office Action, Applicants respectfully submit that it would not be obvious to one skilled in the art to combine Tearney et al., Peterson et al., Izatt et al., and

Swanson et al. in the various combinations because there is no motivation to combine the references suggested in the art. Additionally, the Examiner has not pointed to any prior art that teaches or suggests to combine the disclosures, other than Applicants ' own teaching.

As the Federal Circuit has recognized, obviousness is not established merely by combining references having different individual elements of pending claims. Ex parte Levengood, 28 U.S.P.Q.2d 1300 (Bd. Pat. App. & Inter. 1993). MPEP 2143.01. Rather, there must be some suggestion, outside of Applicants' disclosure, in the prior art to combine such references, and a reasonable expectation of success must be both found in the prior art, and not based on Applicant's disclosure. In re Vaeck, 20 U.S.P.Q.2d 1436 (Fed. Cir. 1991). In the present case, neither a suggestion nor motivation to combine the prior art disclosures, nor any reasonable expectation of success has been shown.

Furthermore, it is impermissible to use the claimed invention as an instruction manual or "template" to piece together the teachings of the cited art so that the claimed invention is rendered obvious. Specifically, one cannot use hindsight reconstruction to pick and choose among isolated disclosures in the art to deprecate the claimed invention. Further, it is impermissible to pick and choose from any one reference only so much of it as will support a given position, to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one of ordinary skill in the art. The present Section 103 rejection appears to be based on a combination of teachings selected from multiple patents in an attempt to arrive at the claimed invention. Since there is no teaching nor suggestion in the cited art for the claimed combination, the Section 103 rejection appears to be based on a hindsight reconstruction in which isolated disclosures have been picked and chosen in an attempt to deprecate the present invention. Of course, such a combination is impermissible, and for this reason, in addition to the reasons given above, Applicants respectfully request that the Section 103 rejection of Claims 5, 6, and 12-18 be withdrawn.

In view of the foregoing remarks, all claims now active in this application are believed to be in condition for allowance. Reconsideration is requested along with early passage to issue. Favorable action and allowance are respectfully solicited. Kindly enter this amendment into the record of this application.

Respectfully submitted,

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